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March 21, 2007

VIA HAND DELIVERY

Honorable Harold A. Ackerman
United States District Court for the District of New Jersey
U.S. P.O. & Courthouse Building, Room 305
Newark, New Jersey 07101

**Re: *Novartis Corp. et al. v. Teva Pharmaceuticals USA, Inc.*,
Civil Action No.: 04-4473 (HAA)(ES)**

***Novartis Corp. et al. v. Watson Laboratories, Inc. et al.*,
Civil Action No. 06-1130 (HAA)(ES)**

Your Honor:

Gibbons P.C., along with White & Case LLP, represents Plaintiffs Novartis Corp. *et al.* ("Novartis") in the above-referenced action.

We write to respectfully request Your Honor's intervention in view of the possible near-term launch of Defendant Teva Pharmaceuticals USA, Inc.'s ("Teva") proposed generic products prior to the resolution of this patent infringement litigation. As discussed below, Teva could receive final approval from the Food and Drug Administration ("FDA") to market generic versions of Novartis' product Lotrel® as early as Monday, March 26, 2007. Should the FDA grant final approval, Teva would be free to launch its proposed generic products even though the infringement issues in this case have not been adjudicated. Novartis would apply for preliminary injunctive relief if this contingency occurs and therefore respectfully requests a conference with Your Honor on or before March 23, 2007 to discuss these issues.

By way of background, the product at issue is Lotrel®, an anti-hypertensive prescription medication manufactured and marketed by Novartis Pharmaceuticals Corporation containing a combination of the agents amlodipine and benazepril. Lotrel® is covered by Novartis' U.S. Patent No. 6,162,802 ("the '802 patent"), the patent-at-issue in this case. Teva filed an Abbreviated New Drug Application ("ANDA") with the FDA seeking to market a generic equivalent of Lotrel® prior to the expiration of the '802 patent. Novartis filed this lawsuit on September 16, 2004, pursuant to 35 U.S.C. § 271(e)(2) alleging infringement of the '802 patent by Teva's proposed products. The filing of the lawsuit gave rise to an automatic 30-month stay under the Hatch-Waxman Act during which time the FDA could not grant Teva final approval to market its generic Lotrel®.¹ 21 U.S.C. § 355(j)(5)(B)(iii). The 30-month statutory stay expired on or about February 6, 2007.

U.S. Patent No. 4,879,303 ("the '303 patent"), assigned to Pfizer Inc., covers the amlodipine component of Lotrel® and is the only other unexpired patent listed in connection with Lotrel®. Teva did not challenge the '303 patent in connection with its ANDA for generic

¹ The FDA granted tentative approval to Teva on July 11, 2006.

GIBBONS P.C.

Honorable Harold A. Ackerman
March 21, 2007
Page 2

Lotrel®, so Teva's ANDA cannot be finally approved until it expires. Because the '303 patent will expire on March 25, 2007, and the statutory 30-month stay has ended, Teva's ANDA could become eligible for final approval as early as March 26, 2007.

Fact and expert discovery in the case were recently completed. No date for a final pretrial conference has been scheduled; nor has a trial date been set.

If the FDA grants final approval, Teva could launch its proposed generic products even though the issues in this case have not been resolved. Such a premature launch would deny Novartis its exclusive right to make, use, and sell products covered by the '802 patent and cause Novartis substantial and irreparable harm. Accordingly, Novartis would file a preliminary injunction application before Your Honor seeking to enjoin Teva from making, using, selling, offering to sell, or importing its proposed generic products until after expiration of the Novartis '802 patent. However, prior to filing such an application, Novartis believes it essential that the Court be involved in determining briefing and hearing deadlines that accommodate both the Court's schedule and the parties' needs. If Teva does not intend to launch prior to the conclusion of this litigation, the issue is obviously moot.

Notably, in other Hatch-Waxman patent cases under similar circumstances, courts (including the District of New Jersey) have suggested and, with the parties' agreement, directed the defendant generic pharmaceutical company to voluntarily notify in writing the court and adversary counsel in advance of any product launch date (e.g. 60-90 days) to provide the court with a reasonable period of time to adjudicate any preliminary injunction application prior to launch. Teva, in fact, recently agreed to such conditions in a Hatch-Waxman litigation pending before Judge Lifland. Given the status of the present action, we respectfully submit that such an approach would also be appropriate here.

We seek the intervention of Your Honor on an emergency basis in view of the time and cost involved for the Court and parties in connection with a possible preliminary injunction application. Novartis had no expectation that Teva would launch "at risk" at this time but heard rumors in the marketplace of a possible launch by Teva. We therefore approached Teva's attorneys as to whether Teva intended to launch its proposed generic product prior to the conclusion of this litigation, and if so, requested that Teva provide advance notice to both Novartis and the Court. In response, Teva refused to indicate whether it intends to launch before final resolution of this case, and refused to provide advance notice of such a launch. Teva instead proposed an exceedingly aggressive briefing and hearing schedule for a preliminary injunction motion and, if Novartis were to consent to it, would agree not to launch until the earlier of the Court's decision on the motion or June 1, 2007. Notwithstanding the needlessly expedited nature of Teva's proposed schedule, Novartis does not believe such a preliminary injunction schedule should be negotiated without the Court's guidance, particularly if Teva refuses to inform the Court and Novartis when it intends to launch.

GIBBONS P.C.

Honorable Harold A. Ackerman
March 21, 2007
Page 3

In light of the urgency of the situation, we respectfully request that Your Honor convene a conference regarding these issues on or before March 23, 2007.

Respectfully,

A handwritten signature in black ink, appearing to read 'David E. De Lorenzi', with a long horizontal stroke extending to the right.

David E. De Lorenzi

cc: Hon. Esther Salas (via facsimile)
Thomas L. Creel, Esq. (via email)
Ira J. Levy, Esq. (via email)
Daryl L. Wiesen, Esq. (via email)
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